

Notice of Allowability

Application No.

09/671,764

Examiner

Chih-Min Kam

Applicant(s)

PISEGNA ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/27/07.
2. ☒ The allowed claim(s) is/are 1-4, 6-10, 20-29 and 32.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 6-10, 20-29 and 31-32 are pending.

Applicants' amendment filed September 27, 2007 is acknowledged. Applicants' response has been fully considered. Claims 1, 6, 7, 9 and 20 have been amended. Therefore, claims 1-4, 6-10, 20-29 and 31-32 are examined.

Oath/Declaration

2. The oath or declaration filed January 11, 2001 is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because alterations to the addresses of inventors, Joseph R. Pisegna, which have not been initialed and dated as are required by 37 CFR 1.52(c). Furthermore, it was requested on 12/19/2006 that the name of Inventor Stephen Wank is deleted due to cancellation of certain claims.

Withdrawn Claim Objections

3. The previous objection to claim 20 and 21 is withdrawn in view of applicant's amendment to the claim in the amendment filed September 27, 2007, and Examiner's Amendment (See below).

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1-4, 6-10, 20, 22-29 and 32 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 5 in the amendment filed September 27, 2007.
5. The previous rejection of claim 31 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Examiner's Amendment (See below).

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tom Hunter on December 3, 2007.

Examiner's Amendment to the Claims:

Cancel claim 31.

Claims 1, 20, 22 and 29 have been amended as follows:

1. (Currently amended) A method of increasing the efficacy of a gastric ~~H⁺/K⁺-ATPase~~ H⁺/K⁺-ATPase pump inhibitor (PPI) in a human in need of a PPI treatment, said method comprising:

injecting into said human an effective amount of one or more agents selected from the group consisting of a pentagastrin, ~~or~~ and a gastrin, in conjunction with an amount of said gastric proton pump inhibitor effective to reduce gastric acid secretion, whereby the efficiency of said gastric proton pump inhibitor is increased.

20. (Currently amended) A kit for the treatment of a pathology characterized by excess gastric acid secretion, said kit comprising:

a container containing a proton pump inhibitor (PPI); and

a container containing one ~~ore~~ or more agents selected from the group consisting of a pentagastrin[~~[,]~~] and a gastrin, wherein the gastrin or pentagastrin is formulated for administration by injection.

22. (Currently amended) The kit of claim 21, wherein said proton pump inhibitor is selected from the group consisting of rabeprazole, omeprazole, lansoprazole, pantoprazole, and congeners ~~and~~ or racemic mixtures thereof.

29. (Currently amended) The kit of claim 21, wherein said kit further comprises instructional materials describing the use of pentagastrin, ~~or gastrin, or an analogue thereof~~ in conjunction with a PPI to reduce gastric acid secretion.

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be the closest art to the claimed invention. Simon *et al.* (Aliment. Pharmacol. Therap. 4, 239-245 (1990)) teach the effects of the H⁺/K⁺-ATPase inhibitor, BY1023/SK&F 96022 on the pentagastrin-stimulated acid secretion (0.6 µg/h/kg) in healthy male volunteers, and intravenous administration of BY1023/SK&F 96022 induced a rapid and dose-dependent inhibition of pentagastrin-stimulated acid secretion, where the inhibitory effect lasted longer than the measurement period, 3 hours. Pentagastrin is continuously infused, and one hour after the start of the pentagastrin infusion, a proper dose of BY1023/SK&F 96022 or placebo is administered intravenously. However, the reference does not teach or suggest the use of an effective amount (i.e., from about 0.1 mg/kg/hr to 10 mg/kg/hr) of pentagastrin to increase the efficiency of the PPI in treating a human patient in need of a PPI treatment. Furthermore, Declaration of Dr. Joseph R. Pisegna filed April 26, 2007 indicates that experiments in a standard mouse model show gastrin enhances the activity of a PPI (see Figure 1), and the enhanced activity is produced by injected gastrin. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

December 3, 2007